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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VAKILI, ZOHREH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,420	LIU ET AL.	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 provides for the use of topical composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US Patent No. 6630163 B1), in view of Murad (US Patent 5962517), and further in view of Gildenburg et al. (US Patent No. 6217852 B1).

Murad (Pat. No. 6630163 B1) teaches that a transition metal component and/or vitamin E may optionally be induced to assist in inhibiting or reducing inflammation (see col. 13, lines 29-31). Murad further teaches that some nonenzymatic antioxidants, such as Vitamin E (tocopherol), Vitamin A (beta-carotene), and Vitamin C (ascorbic acid)

have been individually applied to assist the skin in scavenging free radicals (see col. 1, lines 44-48). The vitamin E component, when included, is typically present in topical formulations in an amount from about 5 to 40 weight percent, preferably from about 6 to 30 weight percent, and more preferably from about 7 to 20 weight percent of the composition (col. 13, lines 36-40). The vitamin C component, when used, is typically present in the pharmaceutical composition in an amount from about 0.1 to 50 weight percent, preferably from about 5 to 40 weight percent, and more preferably from about 10 to 25 weight percent (see col. 14, lines 51-55). Topical formulations of the composition, however, will typically include the vitamin A component in an amount from about 0.5 to 15 weight percent, preferably from about 1 to 10 weight percent (see col. 14, lines 58-65). Murad further teaches the use of fragrance in an amount of 0.01-1.0 weight percent (see col. 24, line 34). Deionized water is metered into a processing tank and high speed mixing is started (see col. 22, lines 1-2).

Murad (Pat. No. 5962517) in this invention teaches a pharmaceutical composition for the treatment of acne having an acne reduction component in an amount sufficient to reduce the redness and blemishes associated with acne. The invention also relates to pharmaceutical compositions having, in addition to the acne reduction component, a skin cell conditioning component in an amount sufficient to properly regulate the keratin and sebum production of the skin cells, thereby inhibiting the appearance of acne. The composition further includes at least one of a vitamin C source, vitamin B complex, and a vitamin E source. The invention also relates to methods for treating acne by administering, alone or in conjunction with another

composition, the pharmaceutical compositions in an amount therapeutically effective in reducing the incidence of acne and methods for additionally inhibiting the appearance of acne by conditioning skin cells (see abstract). Murad further teaches that the acne reduction component is a vitamin A source, a carotenoid component, a vitamin B_6 source, and a zinc component. In a preferred embodiment, the vitamin A source is present in about 0.005 to 5 weight percent, beta-carotene is present in about 0.1 to 10 weight percent (see col. 4, lines 56-65). The vitamin C source is calcium ascorbate present in about 1 to 30 weight percent (see col. 4, lines 18-19). The vitamin E source is present in about 1 to 30 weight percent (see col. 4, lines 29-30). Vitamin B complexes enhance the effectiveness of vitamin B_6 in treating the skin. Vitamin B complexes may be found in the present pharmaceutical composition in about 0.05 to 15 weight percent, preferably about 0.2 to 5 weight percent, and more preferably about 0.3 to 3 weight percent (see col. 8, lines 13-19).

Gildenberg et al. teaches a composition for use as a sunscreen applied during washing (see abstract). Preferred carriers for inclusions with compositions of the present invention include one or more surfactants (see col. 11, lines 29-30). Preferred surfactants include any one of a great variety of nonionic, cationic, anionic, and zwitterionic emulsifiers (see col. 11, lines 39-41). Generally, suitable surfactant types include esters of glycerin, esters of propylene glycol, fatty acid esters of polyethylene glycol, carboxylic acid copolymers (see col. 11, lines 44-48). Gildenberg et al. further teaches the surfactant may be used individually or as a mixture of two or more. Regardless of the number selected the surfactant preferably comprise from about 0.1

percent to 40 percent, preferably from about 1.0 percent to about 20 percent, and most preferably from about 1.0 percent to about 10.0 percent of the composition of the present invention (see col. 12, lines 11-16). The composition of the present invention comprises from about 5.0 percent to about 95.0 percent, more preferably from about 10.0 percent to about 80.0 percent, and most preferably from about 30.0 percent to about 60.0 percent of purified water, according to the American Heritage Dictionary distilled water is purified or refined by distillation. The exact level of water will depend upon the form of the product and the desired moisture content (see col. 12, lines 31-37). Thickening agents or gellants may be added as desired to adjust the texture and viscosity of the composition. Such agents or gallants may be selected from Carbopol® resins and Pemulen® (see col. 13, lines 7-14). Optionally, various vitamins may be included in the composition of the present invention. Examples include vitamin A, vitamin C, vitamin B, and vitamin E (see col. 13, lines 15-23).

It would have been obvious to one skilled in the art to use the teachings of Murad (Pat. No. 6630163 B1) taken with Murad (Pat. No. 5962517) and combined with the teachings of Gildenberg et al. All three references teach that these components, Vitamin E, Vitamin C, carotene, Vitamin B complex are used in combination for topical administration. The motivation to combine the references is because Murad teaches nonenzymatic antioxidants such as Vitamin E (tocopherol), Vitamin A (beta-carotene), and Vitamin C (ascorbic acid) have been individually applied to assist the skin in scavenging free radicals and neutralizing the harmful effects of UV light. Further Murad (Patent No. 5962517) relates to pharmaceutical compositions for treating acne and

conditioning the skin cells by using vitamin C, vitamin B complex, vitamin E, and beta carotene. Gildenberg et al. introduces additional components such as surfactants, thickening agents, and inclusion of vitamin C, vitamin B, vitamin A and vitamin E in the composition of the invention.

The ranges of these ingredients are within the concentration range as presently claimed in the invention. It would have been obvious to one skilled in the art to use the teachings of Murad (Pat. No. 6630163 B1 and Pat. No. 5962517), Gildenberg et al., to modify the concentration ranges to come up with a composition for skin product to help shield the skin and to provide acne treatment.

Therefore, one having ordinary skill in the art at the time of invention was made would have been motivated to use the teachings of the prior arts cited above about the use and making of a composition for skin care as claimed in the present invention.

In the absence of any criticality/unexpected results presently claimed invention is considered *prima facie* obvious over the prior arts for the reasons cited above.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 & 15-17 of serial number 11/446,051.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

In this case, what is claimed in both applications recite a topical composition for transdermal administration in treatment of acne, comedo and zit. Main components of the composition comprise of vitamin C, vitamin B complex, carotene, and vitamin E. The composition further comprises of fragrance, thickening agent and surfactant. Such subject matter of the present claims directly conflicts with the subject matter of the application, serial number 11/446,051 and is not considered to be patentably distinct.

Thus, claims 1-9 are not considered to be patentably distinct over claims 1-10 & 15-17 of application serial number 11/446,051, and are properly rejected under the judicially created doctrine of obviousness-type double patenting as being obvious and unpatentable variants.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
1614

September 25, 2006

Ardin H. Marschel 9/29/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER